

REMARKS/ARGUMENTS

Claims 23, 25-28 and 30, 33, and 35-43 are active in this application.

Amendments to Claim 23 are supported by the specification on page 2, line 13 (microorganism already producing L-amino acid), the Examples (e.g., Example 10 on page 25) for determining the concentration, and Example 1 (pages 13-14) for obtaining the gene with the noted primers.

The objection to claim 24 is no longer applicable as Claim 24 has been cancelled. Claim 42 has been amended as suggested on page 3 of the Action.

The rejection of Claim 34 under 35 USC 112, second paragraph is no longer applicable as the claim has been cancelled.

The rejection of Claims 23-28 and 30-43 under 35 USC 112, first paragraph is respectfully traversed.

Claim 23 has been amended to replace “and/or” with —or—.

Claim 31 has been cancelled and Claim 30 has been amended to list only the *rhtC* and *gdhA* polynucleotides, the supporting description that these are from *E. coli* is found in the Example 6 (page 19 for *rhtC*) and Example 5 (page 17) for *gdhA*. As explicitly descriptive support is found in the specification, the limitations cannot constitute new matter. Withdrawal of his rejection is requested.

The rejection of Claims 23-28, 30-34 and 39-41 under 35 USC 112, first paragraph alleging that the specification does not sufficiently describe the *poxB* gene limitation is respectfully traversed.

As noted previously, the poxB gene which is inactivated is inactivated in an Escherichia microorganism and the specification describing the Escherichia poxB gene and the protein encoded thereby. The claims have also been amended to define that the poxB coding sequence is obtainable by PCR using the specific primers used in Example 1 to isolate the gene and make mutants thereof.

The specification also describes in the first paragraph of page 6 that the sequence of poxB is known (referencing two publications from 1986 and 1987 and a GenBank accession number).

The Examiner contends that the claimed invention cannot be adequately described because the single nucleotide sequence “fails to reflect the wide variation among the members of the genus . . .” see page 5, of the final Official Action. First and notably, there is no evidence to support the allegation that there is indeed wide variation amongst Escherichia poxB coding sequences.

To determine whether an application meets the written description requirement, the Examiner must determine if there is sufficient written description to inform one of ordinary skill in the art that Appellants were in possession of the claimed invention at the time of filing the application (see MPEP 2163). Written description is satisfied, if the specification conveys with reasonable clarity to those skilled in the art, that as of the filing date, Appellants were in possession of the claimed invention (see MPEP 2163). Moreover, the written description need only describe in detail that which is new or not conventional--see MPEP 2163, citing *Hybritech v. Monoclonal Antibodies*, 802 F.2d 1367 (Fed. Cir. 1986).

The specification clearly indicates that the poxB enzyme class by its source (Escherichia), its activity (pyruvate oxidase), and a representative sequence (SEQ ID NOL1), which is known in the art.

The inactivation of poxB enzymes as known in the art, and thus, novelty does not lie in the individual protein or in the DNAs encoding such proteins, but rather in the specific presence of the same in a single cell, to impart catalytic properties upon that cell, as claimed in the invention. Compliance with the written description requirement is essentially a fact-based inquiry that will depend on the nature of the invention claimed (see *Enzo Biochem, Inc., v. Gen-Probe Incorporated*, 323 F.3d, 956, 963, (Fed. Cir. 2002)). The reference cited in the application on page 6 also makes it known that the amino acid sequence was known. Moreover, it is well known that an amino acid sequence of a protein can be reverse-translated into the corresponding DNA (see also *In re Wallach et al*, 03-1327 (Fed. Cir. 2004) – *no reason to require a patent application to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is, ..., a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.*). The permutations of coding sequences based on a reverse translation of the amino acid sequence, in of itself, provides even more than just the nucleotide sequence depicted in SEQ ID NO:1.

The Examiner contends on page 6 of the Action that “there is no requirement that the [inactivated poxB] encode a non-functional polypeptide . . .” and goes on to opine that deletion mutagenesis to deleted 5’ and 3’ nucleotides “would likely not result in the partially deleted poxB gene encoding a non-functional polypeptide.” Notwithstanding the fact that there is no evidence of record to support this contention, it doesn’t make any sense. That is, the claims require an “inactivated poxB” which is achieved by one of three methods. The requirement that poxB is inactivated clearly means that the polypeptide is not functional. If a modification were made to a cell (5’ or 3’) that did not inactivate poxB then it would not be an inactivated poxB as required in the claims.

The adequate written description requirement. . . serves to ensure that the inventor had possession, as of the filing date, of the subject matter later claimed, and how the specification accomplishes this is not material (see *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996)).

Appellants have provided a sufficient disclosure on the description of the techniques used to transform a cell in a manner to produce L-amino acids. Individual enzymes, their respective DNAs, and individual microorganism containing such enzymes are known in the art. In addition, Appellants provided in the specification, a representative protein sequence, and corresponding DNAs for poxB as well as defined structural features depicted as the primers which can be used to amplify the poxB coding sequence—noting that the sequences are specific to poxB and selectively amplify the poxB coding sequence. Therefore, Appellants have provided sufficient written description for the claimed invention.

As the issues pertain to Claims 30 and 31, it is again noted that Claim 31 has been cancelled and Claim 30 has been limited to the two genes used in the Examples, each of which were known, their sequences known and thus the identification of the source implicitly evidences a possession of that portion of the invention (see *Capon v. Eshhar*, 76 USPQ2d 1078 (Fed. Cir. 2005): “*When the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh.*”)

Withdrawal of this rejection is requested.

The rejection of Claims 23-28, 30-34 and 39-41 on the basis of alleged lack of enablement for the claims under 35 USC 112, first paragraph is respectfully traversed.

For the reasons stated above, having demonstrated that the Applicants were, in fact, in possession of the invention as now claimed there really should be no issue as to making and using the invention as claimed. Having provided guidance above, as to how to obtain the coding sequence (e.g., using PCR primers as defined in Claim 23), a representative example

of the coding sequence, which was already known, how to inactivated poxB (as recited in the claims), culturing, determining concentration and isolating, there is no question that the claims are enabled by the specification.

Accordingly, withdrawal of this rejection is requested.

The rejection of Claims 23, 25-28, 33, 40, and 42-43 in view of Chang et al and Claims 23-28, 33, and 41-43 in view of Grabeau et al (and Claim 39 combining Grabeau with Yoder—making a deletion mutant). Both publications appear to describe a mutated/inactivated poxB gene and culturing the bacteria containing this mutation. Admittedly, these publications do not explicitly describe producing L-amino acids or concentrating the L-amino acids. However, the Examiner has taken the position that the cultured bacterium inherently produce L-amino acids and inherently result in some concentration of L-amino acids secreted into the medium. Other than the allegations, the Examiner's assertions are not supported by any evidence or scientific reasoning.

Nonetheless, the aspect of determining the concentration of the L-amino acids, is not explicitly nor inherently found in any of the cited publications. Moreover, one would not have set out to specifically determine the concentration of L-amino acids because the goal of Chang and Grabau is not to produce L-amino acids.

Accordingly, withdrawal of these rejections is requested.

To the provisional rejections under the doctrine of obviousness-type double patenting, Application serial nos. 10/483,416, 10/481,631, 10/616,309, 10/481,823, 10/114,048 and 10/186,999 ([c], [h], [o], [q] [w] and [z]) have been abandoned.

U.S. application 10/1114,073 ([y]) has issued as U.S. patent no. 7,052,883 and a terminal disclaimer is attached hereto addressing this portion of the rejection.

Application No. 10/076,416

Reply to Office Action of July 25, 2006

With respect to the remaining co-pending applications, Applicants request that these rejections be held in abeyance since the alleged conflicting claims have not yet been patented—see MPEP § 822.01.

Should the Examiner wish to discuss any aspect of this application, he is invited to contact the Applicants' undersigned representative.

A Notice of Allowance is requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Daniel J. Pereira, Ph.D.
Registration No. 45,518

Customer Number

22850

Tel: (703) 413-3000

Fax: (703) 413 -2220

(OSMMN 06/04)